SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubiflox 20 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution for injection contains:

Active substance:
Marbofloxacin 20 mg

Excipients:
Metacresol 2 mg
Disodium edetate 0.10 mg
Monothioglycerol 0.50 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, greenish yellow to brownish yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pre-ruminant calves up to 100 kg b.w).
Pigs.

4.2 Indications for use, specifying the target species

Cattle (pre-ruminant calves up to 100 kg b.w)
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma bovis.*

Fattening pigs
Treatment of respiratory infections caused by sensitive strains of *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida.*

4.3 Contraindications

Do not administer in animals with known hypersensitivity to marbofloxacin or any other quinolone or to any of the excipients.

Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
Avoid accidental self-injection, since this can cause local irritation. In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Administration by subcutaneous and intramuscular route may induce transitory oedema. Administration by the intramuscular route may cause pain reaction and inflammatory lesions at the site of injection. Inflammatory lesions persist 6 days in pigs and 12 days in calves.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intramuscular routes in cattle (the first injection may also be given by intravenous route), and by intramuscular route in pigs.
Treatment duration is as follows:
- cattle, IM, SC route: 3 to 5 days
- pigs, IM route: 3 to 5 days

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

The dose volume given at one injection site should not exceed 6 ml in calves, and 3 ml in pigs.

The cap may be safely punctured up to 20 times. The user should choose the most appropriate vial size according to the target species to treat.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No sign of overdose has been observed after administration of 3 times the recommended dose.
Overdose may cause acute signs in the form of neurological disorders which should be treated symptomatically.

4.11 Withdrawal period(s)

Cattle (Pre-ruminant calves up to 100 kg body weight):
Meat and offal: 6 days

Pigs:
Meat and offal: 4 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones,
ATCvet code: QJ01MA93

5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular Staphylococci) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhymurium*, *Campylobacter jejuni*, *Citrobacter*, *Enterobacter*, *Proteus* spp., *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica*, *Mannheimia haemolytica, Pasteurella multocida*, *Histophilus* spp., *Moraxella* spp., *Pseudomonas aeruginosa*) as well as Mycoplasma (*Mycoplasma bovis*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*). Resistance in Streptococcus may occur.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

5.2 Pharmacokinetic particulars

After subcutaneous administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and its bioavailability is close to 100%. It is weakly bound to plasma proteins (less than 10% in pigs and 30% in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, uterus, digestive tract) it achieves higher concentrations than in plasma.
In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ($t_{1/2}\,\beta$ = 5-9 h) predominantly in the active form in urine (3/4) and faeces (1/4).
In pigs, marbofloxacin is eliminated slowly ($t_{1/2}\,\beta$ = 8-10 h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gluconolactone
Disodium edetate
Mannitol
Metacresol
Monothioglycerol
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store in the original package in order to protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Bottle (amber glass type II), bromobutyl rubber stopper, aluminium closure: 50 ml solution for injection, in a box.
Bottle (amber glass. type II), bromobutyl rubber stopper, aluminium closure: 100 ml solution for injection, in a box.

Bottle (amber glass type II), bromobutyl rubber stopper, aluminium closure: 250 ml solution for injection, in a box.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Krka, d.d, Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8. MARKETING AUTHORISATION NUMBER

Vm 01656/4056

9. DATE OF FIRST AUTHORISATION

10 October 2011

10. DATE OF REVISION OF THE TEXT

July 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary prescription.

Approved: 01 July 2016